

### REMARKS

Claims 35-37 have been canceled without prejudice or disclaimer. Applicants reserve the right to file one or more continuation or divisional applications directed to the canceled subject matter. New claims 38-39 has been added. New claim 38 corresponds to canceled claim 36 which has been amended as suggested by the Office in the December 29, 2005 final Office action on page 11, item 11 and in response to the 35 USC 112, second paragraph rejection on page 11, of the December 29, 2005 Office action. New claim 39 corresponds to canceled claim 37, corrected in response to the 35 USC 112, second paragraph rejection on page 11 of the December 29, 2005 Office action. No new matter has been added. Entry of said amendment and reconsideration is respectfully requested.

**The rejection of claims 35 and 37, as it now pertains to new claim 39, under 35 USC 102 (b) as being anticipated by Kanatani et al. is respectfully traversed.**

The Office states that Kanatani et al. disclose bacteriocin produced by *Lactobacillus acidophilus* which is active against closely related lactic acid bacteria and cites page 1061 as evidence. The Office further states that the microorganisms disclosed in the instant specification are characterized by their anti-bacterial properties and cites page 6, paragraph 0007 as evidence. The Office then states that the microorganism disclosed in the prior art is known to display antimicrobial activity and cites page 1061 of Kanatani et al. The Office concludes that inherently, the bacteriocin produced by *Lactobacillus Acidophilus* would have the identifying characteristics of the claimed bacterial strain.

Applicants respectfully submit that Kanatani et al. fails to anticipate new claim 39 which is directed to an isolated *Lactobacillus salivarius* deposited with United States Department of Agriculture, Agriculture Research Service Patent Culture Collection as Accession Number NRRL B-30514. The reference is directed to *Lactobacillus acidophilus* TK9201. Note that *L. acidophilus* is *motile* and paragraph [0039] of the above-identified application describes the *L.*

*salivarius* NRRL-30514 as *nonmotile*. Furthermore the reference is totally silent as to a *Lactobacillus salivarius* strain. The Federal Circuit states that the anticipation determination is viewed from one of ordinary skill in the art and that there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention, *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F. 2d 1565, 18 USPQ2d 1001, 1010, (Fed. Cir. 1991). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. It is not enough, however, that the reference discloses all the claimed elements in isolation. With respect to NRRL B-3051, note that *In re Mancy* states if a strain was unknown to those of ordinary skill in this art area, one cannot choose from the unknown (*In re Mancy*, 182 USPQ, 303, (CCPA, 1974) .

The rejection is improper. Applicants respectfully request withdrawal of the instant rejection.

**The rejection of claims 35 and 37, as it now pertains to new claim 39, under 35 USC 102(b) as being anticipated by Ocana et al is respectfully traversed.**

The Office states that Ocana et al disclose bacteriocins synthesized by bacteria having a narrow spectrum of activity, having the ability to inhibit a wide range gram-positive bacteria citing page 5631 as evidence. The Office further states that in addition, Ocana et al disclose that *L. salivarius* was selected because of its ability to inhibit growth of microorganisms citing page 5632 as evidence.

Applicants respectfully submit that Ocana et al. fails to anticipate the instantly claimed invention. The reference fails to anticipate the claims to an isolated *Lactobacillus salivarius*,

Accession No. NRRL B-30514, since the reference fails to teach this specific strain. The Federal Circuit states that the anticipation determination is viewed from one of ordinary skill in the art and that there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention, *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F. 2d 1565, 18 USPQ2d 1001, 1010, (Fed. Cir. 1991). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. It is not enough, however, that the reference discloses all the claimed elements in isolation. With respect to NRRL B-3051, note that *In re Mancy* states if a strain was unknown to those of ordinary skill in this art area, one cannot choose from the unknown (*In re Mancy*, 182 USPQ, 303, (CCPA, 1974). With respect to a side-by-side comparison, applicants have provided evidence that the two bacteria are different. Note Table 1 of the *Ocana et al.* reference, where *E. coli* and *Klebsiella* were resistant to the disclosed bacteriocin. Note Table 4, for example, of above-referenced specification, which shows that the instantly claimed bacteriocin inhibits growth of *E. coli* and *Klebsiella*. Also note that the activity of the *Ocana et al.* bacteriocin was lost after chymotrypsin treatment but the bacteriocin produced by the instantly claimed bacterial strain retained its activity after chymotrypsin treatment. This evidence would teach one of ordinary skill in the art at the time the claimed invention was made, that the two strains were different since they produce different bacteriocins.

The rejection of claims 35 and 37, as it now pertains to new claim 39, under 35 USC 102(e) as being anticipated by *Collins et al* is respectfully traversed.

The Office states that *Collins et al* discloses probiotic strains of *Lactobacillus salivarius*

and the use of gram positive, catalase negative rod-shaped bacteria isolates and citing page 4, paragraph 0068. The Office then states that by all comparative data the strain of the prior art and the instantly claimed strain, absent evidence to the contrary, are the same and the strain of the prior art inherently anticipates the instantly claimed strain because by applicant's definition in the instant specification, the *Lactobacillus salivarius* pvd 32 is gram positive, catalase negative, and pleomorphic rods citing page 19, 0039. The Office finally states that the strain of the prior art would inherently have identifying characteristics of the claimed strain.

Applicants respectfully submit that the Collins et al reference fails to anticipate the instantly claimed invention. New claim 39 is directed to an isolated *Lactobacillus salivarius* deposited with United States Department of Agriculture, Agricultural Research Service Patent Culture Collection as Accession Number NRRL B-30514. Collins et al fails to teach a *Lactobacillus salivarius* strain having accession number NRRL B-30514. The Federal Circuit states that the anticipation determination is viewed from one of ordinary skill in the art and that there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention, *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F. 2d 1565, 18 USPQ2d 1001, 1010, (Fed. Cir.1991). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. It is not enough, however, that the reference discloses all the claimed elements in isolation. With respect to NRRL B-3051, note that *In re Mancy* states if a strain was unknown to those of ordinary skill in this art area, one cannot choose from the unknown (*In re Mancy*, 182 USPQ, 303, (CCPA, 1974))

The rejection is improper. Applicants respectfully request withdrawal of the instant

rejection.

**The objection to claim 37 for the word "new1" is respectfully traversed.**

New claim 39 which corresponds to canceled claim 37 no longer contains the recitation "new1". Withdrawal of the instant objection is respectfully requested.

**The rejection of claim 35 under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is respectfully traversed.**

Claim 35 has been canceled and no claim has been added of this scope. Withdrawal of the instant rejection is respectfully requested.

**The rejection of claim 36, as it now pertains to new claim 38, under 35 USC 101 as being directed to non-statutory subject matter is respectfully traversed.**

New claim 38 reads "An isolated bacteriocin having SEQ ID NO 1" as suggested by the Office to overcome the instant rejection. Withdrawal of the instant rejection is respectfully requested.

It is believed that all of the claims are in condition for allowance. Accordingly, it is respectfully requested that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

In the event this paper is deemed not timely filed, the undersigned hereby petitions for an appropriate extension of time. The fee for such extension may be charged to Deposit Account 50-2134, along with any additional fees which may be required with respect to this paper.

Respectfully Submitted,

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DATE

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CERTIFICATE OF FILING VIA FACSIMILE

The undersigned hereby certifies that the attached **AMENDMENT UNDER 37 CFR 1.116**, was this day, March 23, 2006, filed in the United States Patent and Trademark Office via facsimile to facsimile number 571-273-8300 Total Pages: 10

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